K083728

AUG 12 2009

Section 5: 510(k) Summary

Submitted by: **InnerOptic Technology, Inc**

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Date of Submission: December 15, 2008

Proprietary Name: InVision System

Common Name: Ultrasonic pulsed echo imaging system

Regulatory Class: Class II per 21 CFR 892.1560

Product Codes: IYO: system, imaging, pulsed echo, ultrasonic
OEW: tracking, soft tissue, intraoperative

Device Description: The InVision System is an accessory to ultrasound systems that provides guidance for the placement of needles or needle-like rigid objects, such as biopsy needles and ablation probes. The system enables a physician to accurately place a needle into a target anatomical structure by overlaying the image of the needle and its predicted future path on the ultrasound image of the internal organs in real time on a stereo monitor, for a "3D" effect (cf. IMAX 3D theaters).

The InVision System consists of four (4) principal components:

(1) a passive infrared position tracking system;
(2) tracking mounts for the ultrasound transducer and the needle;
(3) custom guidance software installed on a computer; and
(4) a stereoscopic monitor with passive glasses for viewing the monitor.

Intended Use: The InVision System is indicated for enhancing the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a

stereoscopic computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualizing such procedures.

Technological characteristics, comparison to predicate device: The technological characteristics and indications for use of the InVision System are the same or similar to those found in the predicate devices. The InVision System is substantially equivalent to the following FDA cleared guidance systems:

System Name	Product Code	510(k) Approval Number
Ultraguide 1000	IYO: system, imaging, pulsed echo, ultrasonic	K974432
IG4 Image Guided System	JAK: system, x-ray, tomography, computed	K060903
Linasys Image-Guided Liver Surgery System	OEW: tracking, soft tissue, intraoperative	K071063
Karl Storz 3D Video System	GCI: laryngoscope, endoscope	K001362

The device labeling contains instructions for use, including indications for use, cautions, contraindications, warnings and planning guidance. This information assures safe and effective use of this device.

Discussion of performance testing: Bench tests were conducted to evaluate the performance characteristics of the InVision System. The results of these studies demonstrate that the InVision System is capable of safely and accurately performing the stated intended use. The results also show similar effectiveness to the Ultraguide 1000 predicate device (K974432).

Conclusion: The InVision System is equivalent to the predicate devices in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Ms. Caroline Green
Quality & Regulatory Manager
InnerOptic Technology, Inc.
106-A North Churton Street
HILLSBOROUGH NC 27278

Re: K083728
Trade/Device Name: InVision System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: July 10, 2009
Received: July 16, 2009

Dear Ms. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: K083728

Device Name: **InVision System**

Indications for Use:

The InVision System is indicated for enhancing the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a stereoscopic computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualizing such procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083728